Exhibit 2

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO WAVE 1 / TVT-O CASES**	**Master File No. 2:12-MD-02327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RULE 26 EXPERT REPORT OF DR. ABBAS SHOBEIRI

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure. All of the opinions that I offer in this Report I hold to reasonable degree of medical or scientific certainty.

I. QUALIFICATIONS

Currently, I am Professor of Obstetrics and Gynecology, Virginia Commonwealth University School of Medicine & George Washington University Professor, Cell Biology & Anatomy, Graduate College, OUHSC, and Vice Chair, Gynecologic Subspecialties, Inova Fairfax Hospital Women's Center. Previously, I was Professor and Section Chief of Female Pelvic Medicine & Reconstructive Surgery and a Professor of Cell Biology and Anatomy at the University of Oklahoma Health Sciences Center.

I was recruited to the University of Oklahoma Health Sciences Center in 2002 as the first fellowship trained physician in Female Pelvic Medicine and Reconstructive Surgery in Oklahoma. Prior to settling in Oklahoma, I obtained my Bachelor degree from the University of Washington in Seattle, Medical Degree from Tufts University in Boston,

and completed my residency and fellowship at Tulane and Louisiana State University in New Orleans. My CV is attached as Exhibit A.

I established the OU Pelvic and Bladder Health Center which now encompasses an ACGME accredited 3 year fellowship program, an International Continence Society and International Urogynecology Association host site for research scholar program, Pelvic Floor Investigation Group (PFIG), OU Basic Science Pelvic Floor Laboratory, and OU International Ultrasound workshop. I have been the recipient of research and educational awards. I have been a grant reviewer for the American College of Obstetrics and Gynecology, the American Urogynecologic Society, and American Federation for Aging Research. I am also a manuscript reviewer for Urology, Journal of Urogynecology & Pelvic Floor Dysfunction, American Journal of Obstetrics and Gynecology, Neurourology & Urodynamics, and Journal of Pelvic Medicine and Surgery. I have authored numerous articles in scientific journals as well as several chapters for textbooks standard to the field of Urogynecology. I am the editor of the textbook entitled: Practical Pelvic Floor Ultrasonography.

I have chaired ultrasound workshops at the International Continence Society, International Urogynecology Association, and multiple institutions around the world. Additionally, I have served on the Research and the Program committees at the American Urogynecologic Society.

My clinical interests include vaginal agenesis and structural abnormalities. My research interests include basic science neuroanatomy and the study of pelvic floor injury using 3D sonography. These include the evaluation and treatment of mesh-related complications.

II. BACKGROUND

The opinions expressed on this report are based on the peer-reviewed medical literature, as well as my experience as an academic urogynecologist with a busy clinical practice. As a urogynecologist and specialist in ultrasound visualization of the pelvic floor, I receive referrals from around the country for mesh-related complications. Patients with mesh-related complications are commonly referred to a tertiary care center for evaluation and treatment because the expertise for repair of these problems requires advanced training. In my current role, I am involved in patient care, teaching, and research.

In addition to my clinical practice treating pelvic organ prolapse and stress urinary incontinence and managing surgical complications, I have special expertise in the imaging of mesh with ultrasound technology. I am recognized as one of the world's experts and have published widely in this area. This expertise provides me with a unique opportunity to visualize the behavior of mesh in vivo and correlate those findings with patient symptoms.

Numerous materials, biologic and synthetic, have been used to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). Three-dimensional ultrasound has been shown to be the most effective technique to image these implantable materials.
X-ray, CT scan, MRI are not capable of visualizing mesh effectively, however 3D ultrasound rays bounce off the mesh material and make the mesh easily visible.

I along with some other world experts popularized a technique for the optimal visualization and pelvic floor imaging of pelvic floor structures, including meshes and implants. The procedure used to obtain these images is similar to the traditional

endovaginal sonogram, but the way the images are obtained is completely different. The traditional endovaginal transducer found in most gynecological imaging is an end-fire transducer. The 3D volumes obtained with a BK side-fire transducer allow for optimal imaging of the vaginal wall, urethra, and anal canal. All images are obtained with a BK Medical 8838 high resolution, 6-12 MHz, 360° rotational transducer. The 8838 has a 65mm X 5.5mm acoustic footprint and penetration depth of up to 85mm. This transducer is similar in size and shape to the traditional end-fire transducer used in gynecological imaging. Pressing the 3D acquisition button moves the internal probe crystals to obtain images every 0.5 degrees for 360 degrees. The images are packaged into a 3D volume that can be manipulated in any plane. The 3D ultrasound imaging takes 30 seconds and minimizes patient discomfort. 2D Ultrasonography is typically extremely operator dependent. 3D imaging allows for an automated acquisition. This reduces operator dependence; the data set is stored and can later be manipulated and analyzed. This methodology has been published and is now widely accepted by the medical community.

I am familiar with the Ethicon prolapse and SUI polypropylene mesh products specifically, in addition to my knowledge relating to mesh products generally. I have personally managed patients with complications related to these devices and have removed TVT-O devices from patients referred to me. I initially used Ethicon's TVT-O but abandoned it because of the high rates of pain complications that I saw in my practice and became apparent in the peer-reviewed medical literature. I have also evaluated patients from other physicians with the same pathology. A patient suffering from groin pain subsequent to TVT-O surgery may not be respond to mesh removal. Managing mesh complications and performing mesh removal surgeries occupy a significant amount of my

professional time. I have removed a significant number of mesh and TVT-O devices since its introduction in 2003, primarily for pain and erosion.

III. SUMMARY OF OPINIONS

1. Mesh complications are unlike those seen with other pelvic surgery in terms of onset, frequency, severity, character, and responsiveness to treatment.

2. Three-dimensional endovaginal ultrasound (EVUS) is a reliable, reproducible, and well-accepted method for assessing pelvic floor conditions, including mesh complications.

3. Mesh complications, including those resulting from transobturator slings, are associated with distinct findings on EVUS.

4. Mesh findings on EVUS include deformation (flat, folding, prominence or convoluted, etc.), shrinkage and contraction, and residual mesh.

5. Mesh contraction (defined by IUGA/ICS as shrinkage or reduction in size) is a well-known occurrence, can be detected by EVUS, and has clinical consequences.

6. The lateral portions of the Gynecare TVT-O of mesh devices are difficult, if not impossible to remove, even with the aid of advanced imaging and surgical skill, and result in significant morbidity for patients.

7. The Gynecare TVT-O is associated with an unacceptably high rate of chronic pain.

8. EVUS evaluation combined with physical examination provides objective evidence of the mechanism and cause of mesh-related symptoms.

9. In a woman presenting with groin pain and/or vaginal/mesh pain and sexual pain following insertion of the TVT-O device, a device-related condition is, more likely than not, the most likely diagnosis on the list of differential diagnoses.

10. In a woman presenting with groin pain and/or vaginal/mesh pain and sexual pain following placement of the TVT-O device, these symptoms are, more likely than not, associated with the material and placement flaws of the TVT-O described in this report.

11. The surgical management of mesh complications requires advanced training and specialized expertise.

12. Timely recognition and referral of mesh complications is of utmost importance to prevent prolonged suffering of patients.

13. Most patients with mesh complications are referred for treatment by someone other than the implanting doctor. This indicates that complications are under-appreciated by community doctors and often results in a delay of appropriate treatment.

14. The TVT-O is defectively designed as described in the body of this report.

15. Ethicon did not adequately warn physicians and patients about known complications and risks associated with its TVT-O device.

16. There are safer alternatives to the TVT-O that have equivalent or superior efficacy.

17. Because of the rate and severity of complications and the lack of improved efficacy over other surgical procedures to treat SUI, the risks of the TVT-O outweigh its benefits and should not be used

IV. TVT-O METHOD OF INSERTION

The Gynecare TVT Obturator ("TVT-O") is an inside-out transobturator sling, the first and only device to be inserted in this fashion. It consists of a ½ X 18 inches strip of PROLENE polypropylene mesh covered by a plastic sheath. PROLENE is an older higher weight, smaller pore mesh designed for abdominal wall hernia repairs. The product description (see Instructions for Use below) states that *when used as a suture*, it has been reported to be non-reactive and to retain its strength indefinitely in clinical use. However, the IFU does not address its reactivity or strength when placed transvaginally in the transobturator space. I saw no evidence that this was tested by Ethicon. Testing of a device in the target space is critical to demonstrate safety - different parts of the body react differently to foreign materials.

The TVT-O is inserted blindly through the following anatomical structures: vaginal epithelium, pubocervical fascia, obturator internus muscle, obturator membrane, obturator externus muscle, adductor magnus muscle, adductor brevis muscle, and gracilis muscle insertion before it exits through the skin. This space contains dense nerves and

blood vessels. Additionally, gynecologists and urologist had no familiarity with the anatomy in this region; there is no other pelvic reconstructive surgery for prolapse or SUI that uses this space other than those using mesh. This represented a radical departure from SUI procedures that utilize the retropubic space.

Ethicon's Instructions for Use (below) describe the procedure. The insertion requires special instruments and is not an easy operation to perform. The trajectory required for placement makes it difficult for surgeons to know where it is being placed and allows a small margin of error. In addition, the anatomy varies from one individual to the next making a one-size-fits-all device unreliable in this space. The TVT-O is inserted through the pubocervical fascia, obturator internus muscle, obturator membrane, obturator externus muscle, adductor magnus muscle, adductor brevis muscle, and gracilis muscle before exiting the skin. Through its course, it passes through or in close proximity to nerves and blood vessels of varying size. Prior to the introduction of transobturator slings and armed trocar-based prolapse mesh "kits", gynecologic surgeons had never operated in this space.

GYNECARE TVT *Obturator* Atraumatic Winged Guide, Sterile Single Use

Please read all information carefully.

Failure to properly follow instructions may result in improper functioning of the device and may lead to injury.

Important:

This package insert is designed to provide instructions for use of the GYNECARE TVT* *Obturator* System, including the GYNECARE TVT *Obturator* device, Helical Passers and Atraumatic Winged Guide. It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT *Obturator* device. These instructions are intended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION

The GYNECARE TVT *Obturator* System is a sterile, single patient use procedure kit consisting of:

GYNECARE TVT Obturator device

The GYNECARE TVT *Obturator* device is a sterile, single patient use device, consisting of one piece of undyed or blue (Phtalocyanine blue, Color index Number 74160) PROLENE* polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm) covered by a plastic sheath overlapping in the middle. Plastic tube receptacles are attached at each end. PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE polypropylene non-absorbable surgical suture. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE mesh is knitted by a process that interlinks each fiber junction and that providing elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

GYNECARE TVT Helical Passers

The GYNECARE TVT Helical Passers are two stainless steel, curved wire passers with plastic handles that are designed to deliver the GYNECARE TVT *Obturator* device. Helical Passers are provided as left and right units, pre-assembled to the GYNECARE TVT *Obturator* device. The Helical Passer MUST not be bent or deformed in any way.

GYNECARE TVT Atraumatic Winged Guide

The GYNECARE TVT Atraumatic Winged Guide is a stainless steel accessory instrument, which facilitates the passage of the GYNECARE TVT Helical Passers through the dissection tract.

INDICATIONS

The GYNECARE TVT *Obturator* device is intended to be used in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

INSTRUCTIONS FOR USE

(Note: hand positions shown in illustrations may vary)

1. Place the patient in the dorsal lithotomy position with the hips hyperflexed over the abdomen. The buttocks should be positioned flush with the edge of the table.
2. The procedure can be carried out under local, regional or general anesthesia.
3. Optionally, the labia may be sutured laterally to provide exposure.
4. Insert a urethral catheter into the bladder and empty the bladder.
5. Mark the exit points of the plastic tubes by tracing a horizontal line at the level of the urethral meatus, and a second line parallel and 2 cm above the first line. Locate the exit points on this line, 2 cm lateral to the folds of the thigh (the skin may be flattened by stretching). Mark the exit points, alternatively a 5–10 mm incision may be made at each exit point or at a later stage of the procedure. *(See Figure 1)*

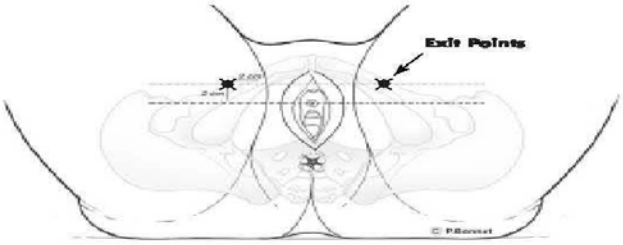

FIG. 1

6. Using Allis clamps for traction, make a 1 cm midline incision in the vaginal mucosa starting 1 cm proximal to the urethral meatus.

(Note: It is suggested that the device insertion be completed on one side before beginning dissection of the second side.)

Using a "push-spread technique", begin blunt dissection preferably using pointed, curved scissors. The path of the lateral dissection should be oriented at a 45° angle from the midline, with the scissors oriented either on the horizontal plane or with the tips pointed slightly upward *(See Figure 2)*. Continue dissection toward the "junction" between the body of the pubic bone and the inferior pubic ramus. *(See Figure 2)*

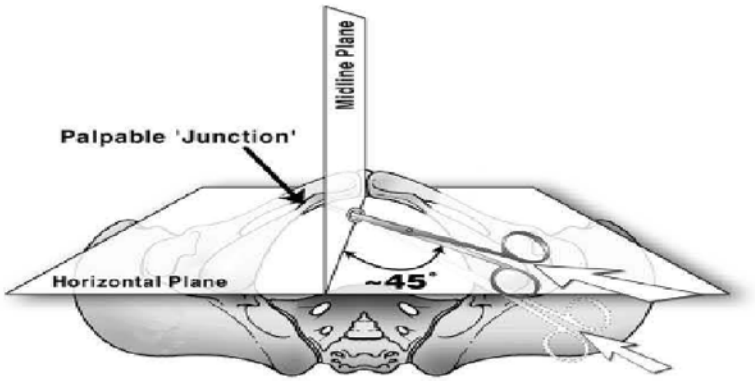

FIG. 2

When the "junction" between the body of the pubic bone and the inferior pubic ramus is reached, perforate the obturator membrane. A loss of resistance can be felt when the membrane is perforated. The channel should be approximately 5–7 mm in diameter and no deeper than 5 cm. Dissection beyond 5 cm may allow unintended entry into the Space of Retzius. If the bone is not reached after dissecting 5 cm, re-evaluate that the angle of dissection is correct.

7. Remove the GYNECARE TVT Winged Guide from the package. *(See Figure 3)*

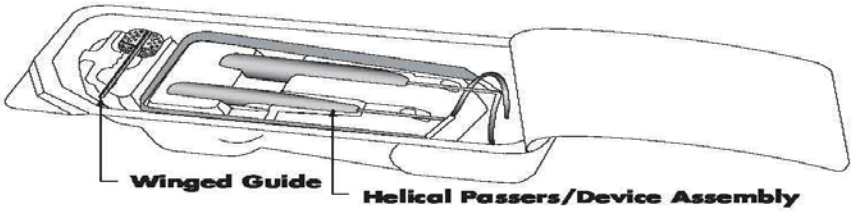

FIG. 3

8. Insert the GYNECARE TVT Winged Guide into the dissected tract until it passes the inferior pubic ramus and enters the opening previously made in the obturator membrane. Loss of resistance can be felt as the Winged Guide passes through the obturator membrane.

If difficulty is encountered during insertion of the guide, reconfirm the direction of the tract with the scissors.

(Note: The open side of the guide must be facing the surgeon. The bendable tab can be bent to increase the length of the guide if needed, See Figure 5.)

9. Remove the GYNECARE TVT Helical Passers/Device Assembly and the GYNECARE TVT *Obturator* device assembly from the sterile pack *(See Figure 3 for components).*

(Note: To ensure correct orientation of the Helical Passers and tape, verify that the GYNECARE logo and thumb indent on the plastic handle are facing the surgeon, and that the points are on the outside facing the surgeon. The Helical Passer in the surgeon's left hand must be used on the patient's right side; See Figure 4.)

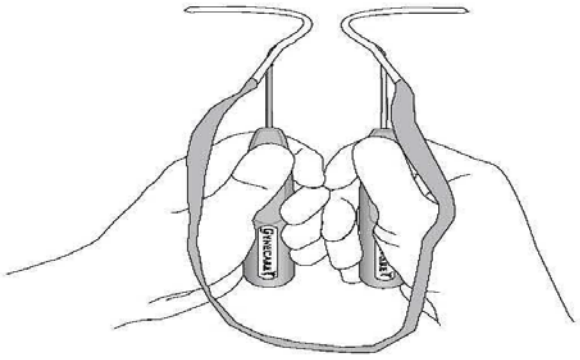

FIG. 4

10. Place one of the Helical Passers on the sterile drape or other suitable sterile location until needed. Assure that the tape is not twisted.

11. Insert the correct GYNECARE TVT Helical Passer into the dissected tract following the channel of the GYNECARE TVT Winged Guide. Push the device inward, traversing, and slightly passing the obturator membrane. Make sure the device handle is oriented so the straight tip of the Helical Passer is aligned with the channel in the GYNECARE TVT Winged Guide and remains in that orientation until the tip traverses the obturator membrane. *(See Figure 5)*

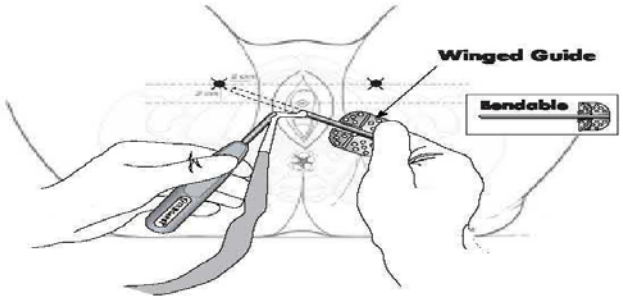

FIG. 5

12. Once in this position, remove the GYNECARE TVT Winged Guide and keep sterile for later use on the same patient.

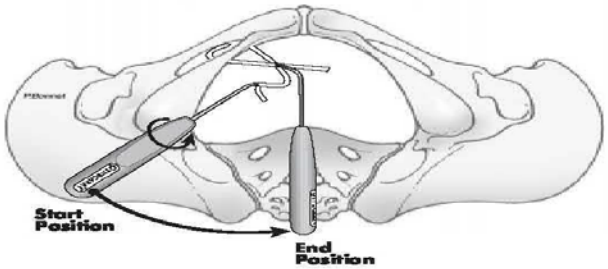

FIG. 6

13. Once the GYNECARE TVT Winged Guide has been removed, rotate the handle of the Helical Passer simultaneously as you move the handle towards the midline. *(See Figure 6)* ***(Note: Never allow the handle to be orientated in a horizontal position.)***

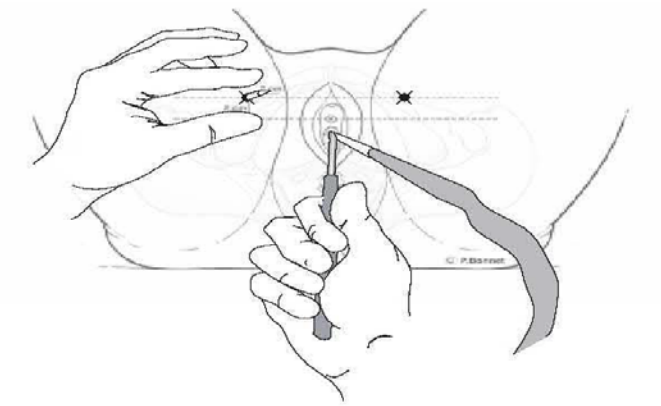

FIG. 7

14. The point of the Helical Passer should exit near the previously determined exit points *(See Figure 7)*. However, slight skin manipulation may be required. If the skin incision has not been previously made, make it at the point where the tip of the helical passer tents the skin. When the tip of the plastic tube appears at the skin opening, grasp it with a clamp and, while stabilizing the tube near the urethra remove the Helical Passer by a reverse rotation of the handle. *(See Figure 8)*

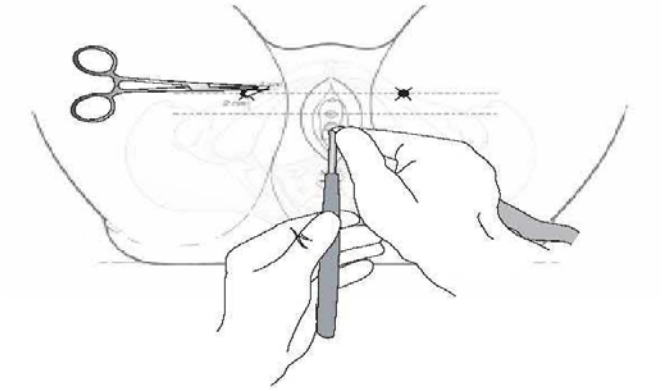

FIG. 8

15. Pull the plastic tube completely through the skin until the tape appears. *(See Figure 9)*

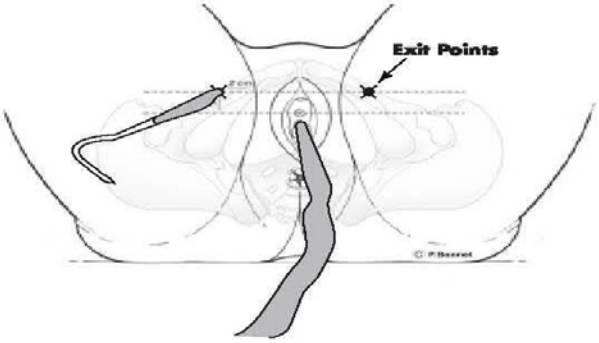

FIG. 9

16. Repeat the technique on the patient's other side ensuring that the tape lies flat under the urethra. *(See Figure 10)*

(Note: If a twist in the tape is discovered, ensure that the twist is not positioned under the urethra after the excess tape is pulled through.)

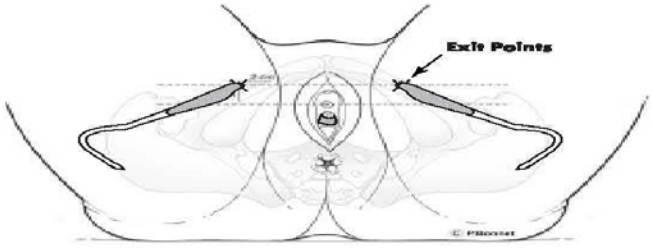

FIG. 10

17. When both plastic tubes have been extracted through the skin incisions, cut the plastic tubes from the tape and plastic sheaths. Position the tape loosely e.g. without tension, and flat under the mid-urethra. At this stage a cough test can be performed. This allows adjustment of the tape so that only a few drops of urine are lost during the cough. (*See Figure 11)*

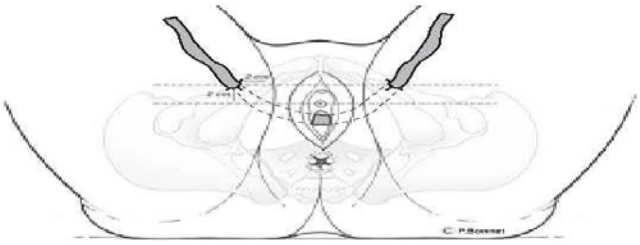

FIG. 11

When the tape is in position, remove the plastic sheath that covers the tapes. To avoid positioning the tape with tension, place a blunt instrument (e.g., scissors or forceps) between the urethra and the tape during removal of the plastic sheaths.

(Note: Premature removal of the sheath may make subsequent adjustments difficult.)

18. Following tape adjustment close the vaginal incision. Cut the tape ends at the exit points just below the skin of the inner thigh. Close the skin incisions with suture or surgical skin adhesive.

19. Cystoscopy can be performed at the discretion of the surgeon. If cystoscopy was performed following the first passage, make sure the bladder is emptied prior to initiating passage of the second side. Post-operative indwelling catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2–3 hours after the operation.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- Do not use GYNECARE TVT *Obturator* procedure for patients who are on anti-coagulation therapy.
- Do not use GYNECARE TVT *Obturator* procedure for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the GYNECARE TVT *Obturator* procedure before employing the GYNECARE TVT *Obturator* device.
- Acceptable surgical practice should be followed for the GYNECARE TVT *Obturator* procedure as well as for the management of contaminated or infected wounds.
- The GYNECARE TVT *Obturator* procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to patient anatomy and correct passage of the device will minimize risks.
- Bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Although bladder injury is unlikely to occur with this technique, cystoscopy may be performed at the discretion of the surgeon.
- Do not remove the plastic sheaths until the tape has been properly positioned.
- Ensure that the tape is placed with no tension under the mid-urethra.
- Do not perform this procedure if you think the surgical site may be infected or contaminated.

- Since no clinical information is available about pregnancy following sub-urethral sling procedure with the GYNECARE TVT *Obturator* System, the patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical information is available about vaginal delivery following a sub-urethral sling procedure with the GYNECARE TVT *Obturator* System, in case of pregnancy delivery via cesarean section should be considered.
- Post-operatively, the patient should be advised to refrain from heavy lifting and/or exercise (e.g., cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can usually return to other normal activity after one or two weeks.
- The patient should be instructed to contact the surgeon immediately if dysuria, bleeding or other problems occur.
- Transient leg pain lasting 24–48 hours may occur and can usually be managed with mild analgesics.
- As with other incontinence procedures, de novo detrusor instability may occur following a sub-urethral sling procedure utilizing the GYNECARE TVT *Obturator* System. To minimize this risk, make sure to place the tape as described above.
- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize GYNECARE TVT *Obturator* device or its components. Discard opened, unused devices.
- Prophylactic antibiotics can be administered according to the surgeon's usual practice.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue, that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

HOW SUPPLIED

The GYNECARE TVT *Obturator* System is provided sterile (ethylene oxide) for single use. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused devices.

STORAGE

Recommended storage conditions for the GYNECARE TVT *Obturator* System single use device are below 25°C, away from moisture and direct heat. Do not use after expiry date.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

V. DISCUSSION

When one looks at the older urogynecology textbooks, the complications of surgical procedures were mostly limited to postoperative medical complications such as postoperative bleeding, pulmonary embolus, myocardial infarctions, and deep venous thrombosis. With the introduction of synthetic materials and mesh kits into vaginal reconstructive surgery over the past decade, unprecedented and unexpected complications have occurred. These are often difficult to manage and require innovative solutions.[1]

The placement of mesh increased rapidly in POP and stress urinary incontinence surgery; however, many complications occurred due to inappropriate techniques dictated by the devices, and many complications were recognized too late and were poorly managed. Ironically, in an effort to avoid bladder injuries associated with retropubic slings which were reversible, manufacturers resorted to a transobturator approach which came with its own set of complications which were not reversible. Many of these techniques, including the Gynecare TVT-O, placed mesh through muscles and densely innervated areas where gynecologic surgeons were not accustomed to operating. Complications unique to mesh (vaginal mesh extrusion, urinary tract erosion, mesh contraction, and chronic pain conditions) have been reported with increasing frequency.[2] Some of these complications are new and unique and require innovative surgeries that may or may not correct the problem. Symptoms of suspected vaginal mesh complications

[1] Giulio Santoro, MD, Pawel Wieczorek, MD, and S. A. Shobeiri, MD. *Endovaginal Three Dimensional Sonography*. Pelvic Floor Disorders 2010.

[2] Abed, H., et al. (2011). "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review." Int Urogynecol J 22(7): 789-798; Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." Neurourol Urodyn.

include vaginal discharge and/or bleeding, dyspareunia, pelvic pain, and recurrent urinary tract infections.

The most common complications associated with mesh procedures, in our experience and as reported in the medical literature, are pain, dyspareunia, erosion, and de novo urinary tract symptoms.[3] These complications are very different from those seen in native tissue pelvic surgery in terms of onset, frequency, severity, character, and responsiveness to treatment. Vaginal mesh exposure, contraction and other complications can be serious and are associated with substantial morbidity. They may result in pelvic/vaginal pain on movement and dyspareunia. In addition, delay in diagnosis can cause chronic problems, which are difficult to treat even after the removal of the mesh. Ultrasound has shown exceptional sensitivity and specificity over physical examination for detection of vaginal mesh.[4] Persistent pain after mesh implantation is a serious matter. It is more likely than not the consequence of nerve entrapment or damage, mesh

[3] Hansen, B. L., et al. (2014). "Long-term follow-up of treatment for synthetic mesh complications." Female Pelvic Med Reconstr Surg 20(3): 126-130; Abbott, S., et al. (2014). "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study." Am J Obstet Gynecol **210**(2): 163 e161-168; Hammett, J., et al. (2014). "Short-term surgical outcomes and characteristics of patients with mesh complications from pelvic organ prolapse and stress urinary incontinence surgery." Int Urogynecol J **25**(4): 465-470; Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." Neurourol Urodyn.; FDA Safety Communication. UPDATE on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. Silver Spring, MD: Food and Drug Administration (US), Center for Devices and Radiological Health. Available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm; Haylen, B. T., et al. (2011). "An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery." Neurourol Urodyn 30(1): 2-12; Lee, D., et al. (2014). "Meshology: a fast-growing field involving mesh and/or tape removal procedures and their outcomes." Expert Rev Med Devices: 1-16; Rogo-Gupta, L. and S. Raz Pain Complications of Mesh Surgery. Complications of Female Incontinence and Pelvic Reconstructive Surgery. H. B. Goldman**:** 87-105; Brubaker, L. and B. Shull (2012). "A perfect storm." Int Urogynecol J **23**(1): 3-4.

[4] Manonai, J., G. Rostaminia, L. Denson, and S. A. Shobeiri. "Clinical and Ultrasonographic Study of Patients Presenting with Transvaginal Mesh Complications." Neurourol Urodyn (Jan 25 2015).

contraction, and scarring. Surgical intervention is often required to alleviate symptoms. It basically involves mobilization of the mesh, division of the fixation arms, and excision of contracted mesh. Apart from possible irreversible damage to the nerve in the case of nerve injury, secondary vaginismus and pelvic floor muscle spasm may occur. Secondary vaginismus is caused by the woman's fear of the pain and is quite difficult to treat.[5]

Many groups have published widely on the evaluation and management of mesh complications resulting from SUI and prolapse procedures. In 2012, our group reported on 133 patients who presented to our clinic for complications of vaginal mesh. The median number of complications per patient was three. The most commonly reported complication was exposure of mesh into the vagina (63.1%). Other complications included: pain (42.8%), infected mesh (6%), dyspareunia (38.3%), vaginal bleeding (24.8%), vaginal discharge (27%), stress urinary incontinence recurrence (29.3%), and pelvic organ prolapse recurrence (25.5%). Some patients had multiple complications. From this study, we determined that the majority (79%) of the patients presenting to our facility were referred by a physician other than the original vaginal mesh surgeon. In our study, the majority of patients with complications secondary to implantation of vaginal mesh who underwent reoperation at tertiary care centers were referrals and had the original implantation performed elsewhere. [6]

[5] Marcus-Braun, N. and P. von Theobald (2010). "Mesh removal following transvaginal mesh placement: a case series of 104 operations." Int Urogynecol J 21(4): 423-430; von Theobald P. Place of mesh in vaginal surgery, including its removal and revision. Best Pract Res Clin Obstet Gynaecol 2011; 25:197–203; Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." Neurourol Urodyn.

[6] Rostaminia, G., et al. (2012). "Referral pattern for vaginal mesh and graft complications to the University of Oklahoma Pelvic and Bladder Health Clinic." J Okla State Med Assoc 105(9): 356-358.

We recently reported a clinical and ultrasonographic study of patients presenting with transvaginal mesh complications which included 79 patients. Of these, 51.9% had vaginal/pelvic pain and 82.2% of sexually active patients had dyspareunia. In this study, we determined that endovaginal ultrasound (EVUS) was helpful in the diagnosis and management of mesh complications.[7] In an abstract submitted for presentation at the 2016 American Urogynecologic Society we have shown that there is simply no rhyme or reason for the course of transobturator slings. Ultrasound shows that there seem to be no way to reliably place them were prescribed.

Multiple publications have determined that three-dimensional endovaginal ultrasound (EVUS) is a reliable, reproducible, and well-accepted method for assessing pelvic floor conditions, including mesh complications. Mesh complications are associated with distinct findings on EVUS.[8] MRI and X-ray imaging have been found to be inferior in their ability to visualize graft materials when compared with ultrasound because they

[7] Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." Neurourol Urodyn.

[8] e.g. Shobeiri A Practical Floor Ultrasonography Springer 2014; Santoro G, Wieczorek A, Shobeiri S, Mueller E, Pilat J, Stankiewicz A, et al. Interobserver and interdisciplinary reproducibility of 3D endovaginal ultrasound assessment of pelvic floor anatomy. Int Urogynecol J. 2010;22:53–9; Santoro GA, Wieczorek AP, Dietz HP, Mellgren A, Sultan AH, Shobeiri SA, et al. State of the art: an integrated approach to pelvic floor ultrasonography. Ultrasound Obstet Gynecol. 2011;37:381–96; Santoro GA, Wieczorek AP, Stankiewicz A, Wozniak MM, Bogusiewicz M, Rechberger T. High-resolution three-dimensional endovaginal ultrasonography in the assessment of pelvic floor anatomy: a preliminary study. Int Urogynecol J Pelvic Floor Dysfunct. 2009;20(10):1213–22. PubMed PMID: 19533007. [English]; Chantarasorn V, Shek KL, Dietz HP. Sonographic appearance of transobturator slings: implications for function and dysfunction. Int Urogynecol J. 2011; 22:493–8; Santoro GA, Wieczorek AP, Shobeiri SA, Mueller ER, Pilat J, Stankiewicz A, et al. Interobserver and interdis- ciplinary reproducibility of 3D endovaginal ultrasound assessment of pelvic floor anatomy. Int Urogynecol J Pelvic Floor Dysfunct. 2011;22:53–9; Santoro GA, Wieczorek AP, Shobeiri SA, Stankiewicz A. Endovaginal ultrasonography: methodology and normal pelvic floor anatomy. In: Santoro GA, Wieczorek AP, Bartram CI, editors. Pelvic floor disorders: imaging and multidisciplinary approach to management. Dordrecht: Springer; 2010. p. 61–78; Santoro GA, Wieczorek AP, Bartram C. Pelvic floor disorders: imaging and multidisciplinary approach to management. 1st ed. Italia: Springer; 2010. p. 729; Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." Neurourol Urodyn.

may visualize swelling and edema associated with mesh but not the mesh itself.[9] Three-dimensional endovaginal ultrasound is a useful tool to evaluate outcomes of surgery with implants, delineate the reason for complications or failure, and plan treatment, especially in patients with a complicated treatment history.[10]

EVUS can be used to determine the location of a mesh device, as well as its deformability and movement with Valsalva. These findings correlate with surgical outcomes. [11] In another abstract submitted for publication at 2016 American Urogynecologic Society meeting, we describe various mesh patterns associated with pain and extrusion. Multicompartment imaging is useful in determining the location and function of synthetic implants.[12] It can help clarify the symptoms of pain and erosion associated with mesh implants. It is also useful in patients with a history of mesh surgery in whom the exact nature of the surgery or the site of mesh placement is unknown. Imaging can be performed preoperatively to understand the intrapelvic course of the mesh implant in order to plan mesh revision surgery better. It can also be performed following mesh removal surgery to determine if there is any mesh left behind. [13] Common mesh findings on EVUS include deformation (flatness, folding, prominence or convoluted, etc.), shrinkage and contraction, fragmentation, migration, and residual mesh.

The most common complication following placement of the TVT-O is pain. The mechanisms leading to pain after TVT-O is multifactorial. A combination of nerve or muscle damage/entrapment and/or tension on vaginal or perivaginal structures as a result

[9] Hegde, A. and Davila, G. W.. Endovaginal Imaging of Vaginal Implants. S. A. Shobeiri: 133-152.
[10] *Id.* at 134.
[11] *Id.* at 139.
[12] *Id.* at 144.
[13] *Id.*

of retraction and scarring are probable explanations. These are findings regularly confirmed on ultrasound and histological examination. For example, Feiner and Maher defined a series of 'mesh contraction' in 17 women surgically managed with mesh excision. All subjects presented with intractable pelvic pain, dyspareunia and tenderness on pelvic examination associated with vaginal scarring.[14] Velemir reported a series of Prolift implants, correlating severe mesh retraction seen ultrasonographically with anterior wall prolapse recurrence.[15] The lateral arms of the TVT-O tape function very much like the arms of a prolapse repair kit.

I reviewed Ethicon documents confirming that Ethicon knew that the TVT-O was associated with more pain than other slings. These included the "confidential" meeting held with prof. de Leval and Ethicon executives just months after the introduction of the product. Concerns about pain complications also provided the main impetus for the development of the TVT Abbrevo. Reported complaints to Ethicon also clearly demonstrated patient and doctor concerns.[16]

Mesh contraction is reported extensively in the medical literature.[17] The FDA, in its 2011 PHN states "*Mesh contraction* (shrinkage) is a *previously unidentified risk* of

[14] Feiner, B. and C. Maher (2010). "Vaginal mesh contraction: definition, clinical presentation, and management." Obstet Gynecol 115(2 Pt 1): 325-330.

[15] Velemir, L., et al. (2008). "Urethral erosion after suburethral synthetic slings: risk factors, diagnosis, and functional outcome after surgical management." Int Urogynecol J Pelvic Floor Dysfunct 19(7): 999-1006.

[16] ETH.MESH.03803462; ETH.MESH.03364532; ETH.MESH.02180759; ETH.MESH.00632022; ETH.MESH.03928235.

[17] Dietz, H. P. E., M.; Shek, K. L. (2011). "Mesh contraction: myth or reality?" Am J Obstet Gynecol 204(2): 173 e171-174; Klinge, U., Klosterhalfen, B., Muller, M., Ottinger, A. P., & Schumpelick, V. (1998). "Shrinking of polypropylene mesh in vivo: an experimental study in dogs." The European Journal of Surgery 164(12): 965-969; Deffieux, X., et al. (2007). "Vaginal mesh erosion after transvaginal repair of cystocele using Gynemesh or Gynemesh-Soft in 138 women: a comparative study." Int Urogynecol J Pelvic Floor Dysfunct 18(1): 73-79; Klosterhalfen, B., et al. (2005). "The lightweight and large porous mesh concept for hernia repair." Expert Rev Med Devices 2(1): 103-117; Gonzalez R., F. K., McClusky D 3rd, Ritter

transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA since the Oct. 20, 2008 *FDA Public Health Notification.*[18] Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." The ICS/IUGA Joint Terminology and Classification of the Complications Related Directly to the Insertion of Prostheses (Meshes, Implants, Tapes) and Grafts in Female Pelvic Floor Surgery lists mesh contraction and defines it as "shrinkage or reduction in size."[19] "Prominence" is defined as "parts that protrude beyond the surface (e.g. due to wrinkling or folding with no

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E.M., Lederman, A., Dillehay D. (2005). "Relationship between tissue ingrowth and mesh contraction." World J Surg 29: 1038-1043; Garcia-Urena, M. A., et al. (2007). "Differences in polypropylene shrinkage depending on mesh position in an experimental study." Am J Surg 193(4): 538-542; Gauruder-Burmester, A., et al. (2007). "Follow-up after polypropylene mesh repair of anterior and posterior compartments in patients with recurrent prolapse." Int Urogynecol J Pelvic Floor Dysfunct 18(9): 1059-1064; Tunn, R., et al. (2007). "Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or rectocele." Ultrasound Obstet Gynecol 29(4): 449-452; Margulies, R. U., et al. (2008). "Complications requiring reoperation following vaginal mesh kit procedures for prolapse." Am J Obstet Gynecol 199(6): 678 e671-674; Feiner, B. and C. Maher (2010). "Vaginal mesh contraction: definition, clinical presentation, and management." Obstet Gynecol 115(2 Pt 1): 325-330; Velemir, L., et al. (2008). "Urethral erosion after suburethral synthetic slings: risk factors, diagnosis, and functional outcome after surgical management." Int Urogynecol J Pelvic Floor Dysfunct 19(7): 999-1006; Mamy, L., et al. (2011). "Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection." Int Urogynecol J 22(1): 47-52; Letouzey, V., Mousty, E., Huberlant, S., Pouget, O., Mares, P., de Tayrac, R. "Utrasonographic Scan Evaluation of Synthetic Mesh Used for Vaginal Cystocele Repair Comparing Four Arms Trans Obturator Techniques to Anterior Bilateral Sacro Spinous Ligament and Arcus Tendinous Suspension." J Minim Invasive Gynecol 17(6): S7–S8; Lefranc, O., Bayon, Y., Montanari, S., *et al.* (2011) Reinforcement Materials in Soft Tissue Repair: Key Parameters Controlling Tolerance and Performance-Current and Future Trends in Mesh Development. In: Von Theobald, P., *et al.*, Eds., *New Techniques in Genital Prolapse Surgery*, Springer Verlag London Ltd., London.

[18] FDA Safety Communication. UPDATE on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. Silver Spring, MD: Food and Drug Administration (US), Center for Devices and Radiological Health. Available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm.

[19] Haylen, B. T., et al. (2011). "An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery." Neurourol Urodyn 30(1): 2-12.

epithelial separation).[20] Although there is one article in the medical literature by Dietz that questions the evidence for mesh contraction, the methodology in this publication is seriously flawed and does not represent generally held opinions.[21]

There are symptoms and conditions that are unique to mesh. For example, exposure and erosion are only seen with synthetic mesh devices. There are also pain syndromes that are unique to mesh. These are often associated with characteristic findings on ultrasound and pelvic examination. When a patient presents with vaginal pain and sexual pain following a mesh procedure, this condition, more likely than not, is caused by mesh and, more likely than not, is mediated by one or more of the mechanisms discussed in this report. The reason is that mesh produces a unique constellation of symptoms that are characteristic of the presence of mesh and virtually not seen in any other setting. Although a differential diagnosis requires looking at all possible explanations for a given constellation of symptoms, there are very few, if any, other medical conditions that produce the same symptoms as mesh – especially when considered in aggregate.[22]

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[20] *Id.*

[21] Dietz, H. P. E., M.; Shek, K. L. (2011). "Mesh contraction: myth or reality?" Am J Obstet Gynecol 204(2): 173 e171-174.

[22] FDA Safety Communication. UPDATE on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. Silver Spring, MD: Food and Drug Administration (US), Center for Devices and Radiological Health. Available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm; Rogo-Gupta, L. and S. Raz Pain Complications of Mesh Surgery. Complications of Female Incontinence and Pelvic Reconstructive Surgery. H. B. Goldman**:** 87-105; Lee, D., et al. (2014). "Meshology: a fast-growing field involving mesh and/or tape removal procedures and their outcomes." Expert Rev Med Devices: 1-16; Novara, G., et al. (2010). "Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence." Eur Urol 58(2): 218-238; Bako, A. and R. Dhar (2009). "Review of synthetic mesh-related complications in pelvic floor reconstructive surgery." Int Urogynecol J Pelvic Floor Dysfunct 20(1): 103-111; Hansen, B. L., et al. (2014). "Long-term follow-up of treatment for synthetic mesh complications." Female Pelvic Med Reconstr Surg 20(3): 126-130; Dunn, G. E., et al. (2014). "Changed women: the long-term impact

Timely recognition and referral of mesh complications is of utmost importance to prevent prolonged suffering of patients. Unfortunately, doctors in the community are often not aware of the risks of mesh. Complications are underreported. Although mesh insertion seems like an easy procedure, the treatment of complications is challenging and surgical management may require specialized expertise. Even in the best of hands, many patients will continue to have symptoms after removal of mesh. Pain is the most difficult condition to treat effectively. Transobturator slings like TVT-O and the arms of prolapse mesh kits (Prolift) are particularly problematic and difficult, if not impossible, to remove in their entirety.[23]

From a clinical perspective, the TVT-O is defectively designed. Features of the TVT-O rendering the product defective include the following:

1. The properties of polypropylene mesh when placed in the transobturator space with the TVT-O device, including chronic inflammation, foreign body reaction, shrinkage/contraction, fibrosis/scarring, hardening, deformation, nerve entrapment, and degradation.

2. The blind passage of synthetic mesh arms through muscle and densely-innervated tissue, resulting in tissue damage and trauma.

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of vaginal mesh complications." Female Pelvic Med Reconstr Surg 20(3): 131-136; Abbott, S., et al. (2014). "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study." Am J Obstet Gynecol 210(2): 163 e161-168; Hammett, J., et al. (2014). "Short-term surgical outcomes and characteristics of patients with mesh complications from pelvic organ prolapse and stress urinary incontinence surgery." Int Urogynecol J 25(4): 465-470; Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." Neurourol Urodyn.

[23] Abbott, S., et al. (2014). "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study." Am J Obstet Gynecol 210(2): 163 e161-168; Danford, J. M., et al. (2015). "Postoperative pain outcomes after transvaginal mesh revision." Int Urogynecol J 26(1): 65-69; Hansen, B. L., et al. (2014). "Long-term follow-up of treatment for synthetic mesh complications." Female Pelvic Med Reconstr Surg 20(3): 126-130. Hammett, J., et al. (2014). "Short-term surgical outcomes and characteristics of patients with mesh complications from pelvic organ prolapse and stress urinary incontinence surgery." Int Urogynecol J 25(4): 465-470.

3. The high, asymmetrical, and unpredictable degree of shrinkage/contraction of the device including the arms.

4. The failure of the central portion of the mesh device to lie flat when there is tension from the arms, resulting in curling, roping, and coiling.

5. The difficulty or impossibility of removing the entire device when complications warrant.

6. The need for multiple surgeries to remove mesh.

7. The chance of persistent symptoms, especially pain, even after the device has been removed.

8. The products can result in late onset of complications that may occur indefinitely into the future.

9. The products cause chronic pain syndromes (resulting from nerve entrapment, scarring, mesh deformation and contraction and inflammation), that are often extremely difficult to treat

I have reviewed and am familiar with the Instructions for the Gynecare TVT-O. I have also reviewed the IFUs for many other medical products throughout my career. To make an informed decision of whether or not to use a particular product, the physician must be warned not only of the potential adverse events that may be associated with the product, but also the frequency, severity, duration and potential permanence of those adverse events. In addition, doctors need this information to adequately inform their patients of the risks and benefits of a given treatment option.

The TVT-O IFU lists the following "ADVERSE REACTIONS":[24]

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.

[24] ETH.MESH.02340829; ETH.MESH.00860239; ETH.MESH.02340974; ETH.MESH.02340756; ETH.MESH.02340902.

- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

In every instance, the reaction listed minimizes the actual risk. "Transient" instead of "permanent". "Potentiate an existing infection instead of "cause". "Punctures of lacerations of nerves" at insertion and "may require surgical repair" instead of chronic nerve trauma and neuropathic pain. Tension only due to "over correction" instead of tension resulting from shrinkage and contraction over time.

The "adverse reactions" listed in the IFU are inadequate to inform doctors and patients of the true risks associated with the TVT-O. Severity, frequency, permanence, and responsiveness to treatment are not addressed. I have personally observed and treated patients who have been implanted with a TVT-O who have experienced the following device-related complications, often severe and life-altering (also reported in the peer-reviewed literature):[25]

[25] Hansen, B., et al., *Long-Term Follow-up of Treatment for Synthetic Mesh Complications*, Female Pelvic Med & Reconstr Surg 2014, 20:126-130; Barski D, et al., *Systematic review and classification of complications after anterior, posterior, apical, and total vaginal mesh implantation for prolapse repair*. Surg Technol Int. 2014, 24:217-24.; Shah, et. al., *Mesh complications in female pelvic floor repair surgery and their management: A systematic review*. Indian J Urol. 2012 Apr; 28(2):129-53; Feiner, B., et al., *Vaginal Mesh Contraction: Definition, Clinical Presentation and Management*, Obstet Gynecol 2010, 115:325-330; Morrisoe, S., et al., *The use of mesh in vaginal prolapse repair: do the benefits justify the risks?* Current Opinion in

- Chronic pain syndromes;
- Chronic inflammation of tissue surrounding mesh;
- Excessive scar plate formation, scar banding, and contracture of mesh arms, resulting in asymmetrical pulling on the central portion, causing pain;
- Erosion of mesh into the bladder and recurrent exposure of mesh in the vagina;
- Pudendal neuralgia and other neuropathies;
- Pelvic floor muscle spasm;
- Nerve damage or nerve entrapment pain as a result of mesh scarification and fibrotic bridging;
- Dyspareunia and sexual impairment;
- Deformed, curled, roped, degraded and fragmented mesh upon removal and visualized with ultrasound;
- Encapsulation of mesh (mesh covered in thick scar);
- Vaginal shortening, tightening, stenosis and/or other deformation;
- Infection as a result of the mesh, including bladder infections, vaginal infections, chronic urinary tract infections, and abscesses;
- Recurrent and persistent vaginal erosion and extrusion and visceral erosion;
- De novo urinary symptoms;
- "Hispareunia".

Under ACTIONS, the IFU states that "animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues which is transient and

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Urology 2010, 20:275-279; Blandon, et al., *Complications from vaginally placed mesh in pelvic reconstructive surgery*, Int Urogynecol J 2009, 20:523-31; Jacquetin, B, *Complications of Vaginal Mesh: Our Experience*, Int Urogyn J, 2009, 20:893-6; Margulies et al, *Complications requiring reoperation following vaginal mesh kit procedures for prolapse*, Am J Obstet Gynecol December 2008; Blaivas, J. G., R. S. Purohit, M. S. Benedon, G. Mekel, M. Stern, M. Billah, K. Olugbade, R. Bendavid, and V. Iakovlev. "Safety Considerations for Synthetic Sling Surgery." Nat Rev Urol 12, no. 9 (Sep 2015): 481-509.

is followed by the deposition of a thin layer of tissue, that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes." These statements are misleading and inaccurate based on the information known to Ethicon from internal documents and the peer-reviewed scientific literature.[26] This information is critical for doctors to know and understand in order to advise their patients of the risks of the permanently implanted device.

There are safer alternatives than the TVT-O that are at least as effective. Adoption of one or more of these alternatives would have reduced or avoided the foreseeable risks of harm that the TVT-O posed. Failure to utilize one or more of these alternatives rendered the devices not reasonably safe and caused or substantially contributed to the complications and injuries discussed in this report.

Based upon my education, training, experience and knowledge, and my familiarity with the published literature relating to this subject, it is my professional

[26] e.g. Klinge, U., Klosterhalfen, B., Muller, M., Ottinger, A. P., & Schumpelick, V. "Shrinking of Polypropylene Mesh in Vivo: An Experimental Study in Dogs." The European Journal of Surgery 164, no. 12 (1998): 965-69; Klosterhalfen B, Linge U, Rosch R, Junge K. "Long-Term Inertness of Meshes." In Meshes: Benefits and Risks. Germany: Schumpelick V, Nyhus L, 2003; Costello, C. R., S. L. Bachman, B. J. Ramshaw, and S. A. Grant. "Materials Characterization of Explanted Polypropylene Hernia Meshes." J Biomed Mater Res B Appl Biomater 83, no. 1 (Oct 2007): 44-9; Clave, A., H. Yahi, J. C. Hammou, S. Montanari, P. Gounon, and H. Clave. "Polypropylene as a Reinforcement in Pelvic Surgery Is Not Inert: Comparative Analysis of 100 Explants." Int Urogynecol J 21, no. 3 (Mar 2010): 261-70; Iakovlev V., Mekel G., Blaivas J. "Pathological Findings of Transvaginal Polypropylene Slings Explanted for Late Complications: Mesh Is Not Inert [Abstract]." International Continence Society Meeting Annual Meeting (2014); Blaivas, J. G., R. S. Purohit, M. S. Benedon, G. Mekel, M. Stern, M. Billah, K. Olugbade, R. Bendavid, and V. Iakovlev. "Safety Considerations for Synthetic Sling Surgery." Nat Rev Urol 12, no. 9 (Sep 2015): 481-509. Smith, T. M., S. C. Smith, J. O. Delancey, D. E. Fenner, M. O. Schimpf, M. H. Roh, and D. M. Morgan. "Pathologic Evaluation of Explanted Vaginal Mesh: Interdisciplinary Experience from a Referral Center." Female Pelvic Med Reconstr Surg 19, no. 4 (Jul-Aug 2013): 238-41.

opinion to a reasonable degree of medical certainty that the injuries and complications that I have personally observed, diagnosed and treated associated with the TVT-O are directly attributable to the defective design of these products as described previously. Because of the unique complications, especially chronic pain, associated with the TVT-O, the difficulty removing when problems arise, and the availability of safer alternatives, it is my opinion that the risks of the TVT-O outweigh the benefits. This is why I, and many of my colleagues in academic centers, no longer use TVT-O in practice. However, I continue to see complications from these devices placed by community doctors. As we have reported, some community doctors, who frequently rely on information from medical device companies, may lack an appreciation of the nature and severity of mesh-induced complications. We have shown that patients who have had mesh complications typically don't follow-up with the physician who performed the initial surgery. As such the physicians may remain unaware of the number or the extent of complications arising from their TVT-O procedures.

Dated: January 29, 2016

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